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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,186	06/29/2001	Joshua Levin	PB/5-31481A	9567

22847 7590 01/28/2005

SYNGENTA BIOTECHNOLOGY, INC.

PATENT DEPARTMENT

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EXAMINER

MEHTA, ASHWIN D

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/896,186

Applicant(s)

LEVIN ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-28,38,39,44,47,51,52 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-28,38,39,44,47,51,52 and 58-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2004 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The objections to claims 47, 53, and 54 are withdrawn, in light of the claim amendments or cancellations.
4. The rejection of claims 44, 47, and 53 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph is withdrawn, in light of the claim amendments.
5. The rejection of claims 25-28, 38, 39, 44, 47, 53, 54, 58, and 59 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, is withdrawn in light of the claim amendments or cancellations.

### ***Claim Objections***

6. Claim 60 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The claim attempts to limit the transgenic plant cell of claim 25 by requiring the endogenous nucleotide sequence to be SEQ ID NO: 23. However, claim 25 indicates that the endogenous nucleotide sequence is to comprise a mutation. SEQ ID NO: 23 is not a mutated sequence.

***Claim Rejections - 35 USC § 112***

7. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim indicates that the endogenous nucleotide sequence encoding SEQ ID NO: 24 is SEQ ID NO: 23. However, SEQ ID NO: 23 is a cDNA sequence, and the definition for “endogenous” on page 17 of the specification reads, “An “endogenous” nucleotide sequence refers to a nucleotide sequence which is present in the genome of the untransformed plant cell.

8. Claims 25-28, 38, 39, 44, 47, 58, and 59 remain and claims 51, 52, and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the

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reasons of record stated in the Office action mailed August 5, 2004. Applicants traverse the rejection in the paper submitted November 5, 2004. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the claims have been amended and claims 53 and 54 have been cancelled (response, page 8, 3<sup>rd</sup> full paragraph). However, again, the specification does not describe any transgenic plant comprising any kind of mutation in an endogenous nucleotide sequence encoding SEQ ID NO: 24, or any regulatory region thereof. The specification does not even describe the gene encoding SEQ ID NO: 24. While the specification includes a discussion on methods for mutagenesis (pages 29-31), it does not describe any plant cell comprising any mutation in any endogenous nucleotide sequence encoding SEQ ID NO: 24. See *Fiers v. Revel* 25 USPQ 2d (CAFC 1993) at 1606, which states that an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself."

9. Claims 25-28, 38, 39, 44, 47, 58, and 59 remain and claims 51, 52, and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed August 5, 2004. Applicants traverse the rejection in the paper submitted November 5, 2004. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the claims have been amended to delete the recitation of "having 98% sequence similarity and encoding a protein having 3'-5' exonuclease activity" (response, page 9, 1<sup>st</sup> full paragraph). However, the specification does not teach a single mutation of any endogenous nucleotide sequence encoding SEQ ID NO: 24. Applicants argue that even though Examples 5 and 9 are written in the present tense, that results from the work performed in Example 5 is set forth in Table 3 (response, page 9, 3<sup>rd</sup> full paragraph). However, the results in Table 3 involve plants produced in Example 2. That example, also written in the present tense, discusses the detection of a T-DNA insertion into SEQ ID NO: 1 using specific PCR primers. A nucleotide sequence encoding SEQ ID NO: 24 was not mutated, and the specification does not teach specific PCR primers corresponding to the sequence of the gene encoding SEQ ID NO: 24, which are needed to perform the PCR.

Applicants also provide post-filing art, Glazov et al. (Plant J., 2003, Vol. 35, pages 342-349), and argue that it describes work related to the instant application. Applicants argue that Glazov et al. describe a cDNA encoding instant SEQ ID NO: 24, analysis of T-DNA insertion of mutant wex-1, characterization of PTGS, complementation experiments and examination of a possible effect of the wex-1 mutation on PTGS (response, page 9, 3<sup>rd</sup> full paragraph). However, it is not clear that the gene, in which the T-DNA insert was detected in instant Example 2, is the same as that described in Glazov et al. Instant Example 2 indicates that the insertion was in SEQ ID NO: 1, which encodes SEQ ID NO: 2. SEQ ID NO: 24 is not the same as SEQ ID NO: 2. Therefore it is not clear that the work described in Glazov et al. discusses the same experiments of the instant examples. Even if the experiments are the same, the specification does not teach any other mutation. Further, and if the experiments of Glazov et al. are the same, Glazov et al.

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teach that the mutant lines, which are homozygous for the mutation, are complemented by insertion of WEX cDNA (page 345). Therefore, insertional mutagenesis of only one chromosomal copy of the endogenous nucleotide sequence, as encompassed by the claimed plants and methods, will not suffice to increase expression of a nucleotide sequence of interest. The T-DNA insert must be present in all copies.

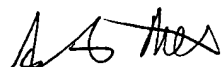
10. Claims 25-28, 38, 39, 44, 47, 51, 52, and 58-60 are rejected.

#### ***Contact Information***

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

January 26, 2005



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Primary Examiner  
Art Unit 1638